

**Outcomes - CVD (Forms 121, 126, 132)****Data File:** ocvd_ep_fu_pub**File Date:** 04/06/2006 **Structure:** One row per participant**Population:** E+P participants

Participant ID**Variable #** 1**Usage Notes:** none**Sas Name:** ID**Categories:** Study: Administration**Sas Label:** Participant ID**Type:** Continuous

ECG pattern

ECG pattern (Form 121)

Variable # 2**Usage Notes:** Associated with clinical MI**Sas Name:** ECGPATT**Categories:** Medical History: Cardiovascular
Outcome**Sas Label:** ECG pattern**Type:** Categorical**Values**

1	Evolving Q-wave and evolving ST-T abnormalities
2	Equivocal Q-wave evol; evol ST-T abnormality; new left LBBB
3	Q-waves or ST-T abnormalities suggestive of an MI
8	Other ECG pattern, ECG uncodable, or normal ECG pattern
9	ECG not available

Centrally adjudicated clinical MI

Centrally adjudicated clinical myocardial infarction (MI)

Variable # 3**Usage Notes:** none**Sas Name:** MI**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Central adj clinical MI**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to clinical MI

Days from randomization to clinical myocardial infarction (MI)

Variable # 4**Usage Notes:** none**Sas Name:** MIDY**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Days from rand to clinical MI**Type:** Continuous

**Central adj non-fatal MI including definite silent**

Centrally adjudicated non-fatal MI including definite silent MI

Variable # 5**Sas Name:** NOFATMI**Sas Label:** Central adj nonfatal MI including definite silent MI**Type:** Categorical**Usage Notes:** Non-fatal defined as no definite coronary death occurring within 28 days of MI.**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Values**

0	No
1	Yes

Days from rand to non-fatal MI include def silent

Days from randomization to non-fatal MI including definite silent MI

Variable # 6**Sas Name:** NOFATMIDY**Sas Label:** Days from rand to nonfatal MI including def silent MI**Type:** Continuous**Usage Notes:** Non-fatal defined as no definite coronary death occurring within 28 days of MI.**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Central adj non-fatal MI excluding definite silent**

Centrally adjudicated non-fatal MI excluding definite silent MI

Variable # 7**Sas Name:** NOFATMI2**Sas Label:** Central adj nonfatal MI excluding definite silent MI**Type:** Categorical**Usage Notes:** Non-fatal defined as no definite coronary death occurring within 28 days of MI.**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Values**

0	No
1	Yes

Days from rand to non-fatal MI exclude def silent

Days from randomization to non-fatal MI excluding definite silent MI

Variable # 8**Sas Name:** NOFATMI2DY**Sas Label:** Days from rand to nonfatal MI excluding def silent MI**Type:** Continuous**Usage Notes:** Non-fatal defined as no definite coronary death occurring within 28 days of MI.**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Centrally adjudicated definite silent MI****Variable #** 9**Sas Name:** DSMI**Sas Label:** Central adj definite silent MI**Type:** Categorical**Usage Notes:** Determined by serial electrocardiography.**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Values**

0	No
1	Yes

**Days from randomization to definite silent MI****Variable #** 10**Usage Notes:** Determined by serial electrocardiography.**Sas Name:** DSMIDY**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Days from rand to definite silent MI**Type:** Continuous

Centrally adjudicated possible silent MI**Variable #** 11**Usage Notes:** Determined by serial electrocardiography.**Sas Name:** PSMI**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Central adj possible silent MI**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to possible silent MI**Variable #** 12**Usage Notes:** Determined by serial electrocardiography.**Sas Name:** PSMIDY**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Days from rand to possible silent MI**Type:** Continuous

Centrally adjudicated coronary death

Centrally adjudicated coronary death (definite or possible coronary death)

Variable # 13**Usage Notes:** none**Sas Name:** CORDTH**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Central adj coronary death (definite or possible coronary death)**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to coronary death

Days from randomization to coronary death (definite or possible coronary death)

Variable # 14**Usage Notes:** none**Sas Name:** CORDTHDY**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Days from rand to coronary death**Type:** Continuous

**CHD (clinical MI, def silent MI, coronary death)**

CHD (clinical MI, definite silent MI, or coronary death)

Variable # 15**Usage Notes:** none**Sas Name:** CHD**Sas Label:** CHD (clinical MI, definite silent MI, or coronary death)**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to CHD

Days from randomization to CHD (clinical MI, definite silent MI, or coronary death)

Variable # 16**Usage Notes:** none**Sas Name:** CHDDY**Sas Label:** Days from rand to CHD**Categories:** Medical History: Cardiovascular
Outcome**Type:** Continuous

Locally adjudicated hospitalized angina

Locally adjudicated angina pectoris (including unstable angina) requiring and/or occurring during hospitalization

Variable # 17**Usage Notes:** Angina occurring on or after the same date as an MI was not counted since reporting of such events was not required by the study protocol.**Sas Name:** ANGINA**Sas Label:** Local adj hospitalized angina**Type:** Categorical

Survival type analyses using angina as the endpoint should consider censoring the survival time at the date of MI if it occurred.

Values

0	No
1	Yes

Categories: Medical History: Cardiovascular
Outcome: Adjudicated**Days from randomization to hospitalized angina**

Days from randomization to angina pectoris (including unstable angina) requiring and/or occurring during hospitalization

Variable # 18**Usage Notes:** Angina occurring on or after the same date as an MI was not counted since reporting of such events was not required by the study protocol.**Sas Name:** ANGINADY**Sas Label:** Days from rand to hospitalized angina**Type:** Continuous

Survival type analyses using angina as the endpoint should consider censoring the survival time at the date of MI if it occurred.

Categories: Medical History: Cardiovascular
Outcome: Adjudicated

**Outcomes - CVD (Forms 121, 126, 132)****Data File:** ocvd_ep_fu_pub**File Date:** 04/06/2006 **Structure:** One row per participant**Population:** E+P participants

Angina based on physician diagnosis and treatment

Angina pectoris (including unstable angina) based on: Physician diagnosis of angina and receiving medical treatment at discharge, for angina on this admission (e.g. nitrate, beta-blocker, or calcium-channel blocker)

Variable # 19**Usage Notes:** none**Sas Name:** ANGINADX1**Sas Label:** Angina - phys dx & tx**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Angina based on diagnosis, treatment, and revasc

Angina pectoris (including unstable angina) based on: Physician diagnosis of angina and receiving medical treatment for angina on this admission plus current medical record documenting a history of coronary heart disease by previous catheterization or revascularization procedure.

Variable # 20**Usage Notes:** none**Sas Name:** ANGINADX2**Sas Label:** Angina - phys dx & tx + prior revasc**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Angina based on CABG surgery or other revasc proc

Angina pectoris (including unstable angina) based on: CABG surgery or other revascularization procedure on this admission

Variable # 21**Usage Notes:** none**Sas Name:** ANGINADX3**Sas Label:** Angina - current CABG/revasc**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Angina based on 70%+ obstruction of coronary arter

Angina pectoris (including unstable angina) based on: 70% or greater obstruction of any coronary artery on angiography on this admission

Variable # 22**Usage Notes:** none**Sas Name:** ANGINADX4**Sas Label:** Angina - current 70%+ obstruction**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

**Angina based on ST effect by stress test with pain**

Angina pectoris (including unstable angina) based on: Horizontal or down-sloping ST-segment depression or abnormal ST elevation ≥ 1 mm on exercise or pharmacological stress testing with pain on this admission.

Variable # 23**Usage Notes:** none**Sas Name:** ANGINADX5**Sas Label:** Angina - ST dep/abn elev**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Angina based on stress test positive for ischemia

Angina pectoris (including unstable angina) based on: Scintigraphic or echocardiographic stress test positive for ischemia on this admission.

Variable # 24**Usage Notes:** none**Sas Name:** ANGINADX6**Sas Label:** Angina - scintigraphic/echocard +**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Angina based on resting ECG ST effect with pain

Angina pectoris (including unstable angina) based on: Resting ECG shows horizontal or down-sloping ST-segment depression or abnormal ST elevation ≥ 1 mm with pain that is not present on ECG without pain on this admission.

Variable # 25**Usage Notes:** none**Sas Name:** ANGINADX7**Sas Label:** Angina - resting ECG ST dep/abn elev**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Locally adjudicated confirmed angina

Locally adjudicated confirmed angina (stress test positive or obstructive coronary disease)

Variable # 26**Usage Notes:** Angina occurring on or after the same date as an MI was not counted since reporting of such events was not required by the study protocol.**Sas Name:** CONFANG**Sas Label:** Local adj confirmed angina (stress test + or obs coronary disease)

Survival type analyses using angina as the endpoint should consider censoring the survival time at the date of MI if it occurred.

Type: Categorical**Values**

0	No
1	Yes

Categories: Medical History: Cardiovascular
Outcome: Adjudicated

**Days from randomization to confirmed angina**

Days from randomization to confirmed angina (stress test positive or obstructive coronary disease)

Variable # 27**Sas Name:** CONFANGDY**Sas Label:** Days from rand to confirmed angina**Type:** Continuous**Usage Notes:** Angina occurring on or after the same date as an MI was not counted since reporting of such events was not required by the study protocol.

Survival type analyses using angina as the endpoint should consider censoring the survival time at the date of MI if it occurred.

Categories: Medical History: Cardiovascular
Outcome: Adjudicated

Acute coronary syndrome (ACS)**Variable #** 28**Sas Name:** ACS**Sas Label:** Acute coronary syndrome (ACS)**Type:** Categorical**Usage Notes:** Defined as hospitalization for angina, Q-wave infarction or non-Q-wave infarction.**Categories:** Medical History: Cardiovascular
Outcome**Values**

0	No
1	Yes

Days from randomization to acute coronary syndrome**Variable #** 29**Sas Name:** ACSDY**Sas Label:** Days from rand to ACS**Type:** Continuous**Usage Notes:** ACS is defined as hospitalization for angina, Q-wave infarction or non-Q-wave infarction.**Categories:** Medical History: Cardiovascular
Outcome**Acute coronary syndrome category****Variable #** 30**Sas Name:** ACSCAT**Sas Label:** Acute coronary syndrome (ACS) category**Type:** Categorical**Usage Notes:** ACS is defined as hospitalization for angina, Q-wave infarction or non-Q-wave infarction.**Categories:** Medical History: Cardiovascular
Outcome**Values**

0	No ACS
1	Unstable angina
2	Non Q-wave MI
3	Q-wave MI

Locally adjudicated congestive heart failure

Locally adjudicated congestive heart failure requiring and/or occurring during hospitalization. (Physician diagnosis of new-onset or worsened congestive heart failure on this admission).

Variable # 31**Sas Name:** CHF**Sas Label:** Local adj congestive heart failure**Type:** Categorical**Usage Notes:** none**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Values**

0	No
1	Yes

**Outcomes - CVD (Forms 121, 126, 132)****Data File:** ocvd_ep_fu_pub**File Date:** 04/06/2006 **Structure:** One row per participant**Population:** E+P participants

Days from randomization to congestive heart fail

Days from randomization to congestive heart failure

Variable # 32**Usage Notes:** none**Sas Name:** CHF DY**Sas Label:** Days from rand to congestive heart failure**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

Locally adjudicated coronary revascularization

Locally adjudicated coronary revascularization. Coronary artery bypass graft (CABG), percutaneous transluminal angioplasty (PTCA), coronary stent, or coronary atherectomy.

Variable # 33**Usage Notes:** none**Sas Name:** REVASC**Sas Label:** Local adj revascularization (CABG or PTCA)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to revascularization

Days from randomization to coronary revascularization. Coronary artery bypass graft (CABG), percutaneous transluminal angioplasty (PTCA), coronary stent, or coronary atherectomy.

Variable # 34**Usage Notes:** none**Sas Name:** REVASCDY**Sas Label:** Days from rand to revascularization (CABG or PTCA)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

Locally adjudicated carotid artery disease (CAD)

Locally adjudicated carotid artery disease requiring and/or occurring during hospitalization. Disease must be symptomatic and/or requiring intervention (i.e. vascular or surgical procedure).

Variable # 35**Usage Notes:** CAD occurring on or after the same date as a stroke was not counted since reporting of such events was not required by the study protocol.**Sas Name:** CAD**Sas Label:** Local adj carotid artery disease (CAD)**Type:** Categorical

Survival type analyses using CAD as the endpoint should consider censoring the survival time at the date of stroke if it occurred.

Values

0	No
1	Yes

Categories: Medical History: Cardiovascular
Outcome: Adjudicated

**Days from randomization to carotid artery disease**

Days from randomization to carotid artery disease requiring and/or occurring during hospitalization. Disease must be symptomatic and/or requiring intervention (i.e. vascular or surgical procedure).

Variable # 36**Sas Name:** CADDY**Sas Label:** Days from rand to CAD**Type:** Continuous**Usage Notes:** CAD occurring on or after the same date as a stroke was not counted since reporting of such events was not required by the study protocol.

Survival type analyses using CAD as the endpoint should consider censoring the survival time at the date of stroke if it occurred.

Categories: Medical History: Cardiovascular
Outcome: Adjudicated

Carotid artery disease (CAD) diagnosis**Variable #** 37**Sas Name:** CADDIAG**Sas Label:** CAD diagnosis**Type:** Categorical**Usage Notes:** none**Categories:** Medical History: Cardiovascular
Outcome**Values**

1	Carotid artery occlusion w/o document of cerebral infarction
2	Carotid artery occlusion w/ document of cerebral infarction

CAD based on hospital discharge summary

Carotid artery disease based on: Symptomatic disease with carotid artery disease listed on the hospital discharge summary.

Variable # 38**Sas Name:** CADHSP**Sas Label:** CAD based on symp disease w/ CAD listed on hospital discharge summary**Type:** Categorical**Usage Notes:** none**Categories:** Medical History: Cardiovascular
Outcome**Values**

0	No
1	Yes

CAD based on carotid angiogram or doppler flow

Carotid artery disease based on: Symptomatic disease with abnormal findings ($\geq 50\%$ stenosis) on carotid angiogram or doppler flow study.

Variable # 39**Sas Name:** CADANGIO**Sas Label:** CAD based on symp disease w/ abnormal findings on carotid angiogram or doppler flow study**Type:** Categorical**Usage Notes:** none**Categories:** Medical History: Cardiovascular
Outcome**Values**

0	No
1	Yes

**CAD based on vascular or surgical procedure**

Carotid artery disease based on: Vascular or surgical procedure to improve flow to the ipsilateral brain.

Variable # 40**Usage Notes:** none**Sas Name:** CADSURG**Sas Label:** CAD based on vascular or surgical procedure to improve flow to ipsilateral brain**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Locally adjudicated HERS like CAD

Locally adjudicated HERS like CAD with or without stroke and surgical or vascular procedure.

Variable # 41**Usage Notes:** none**Sas Name:** HERSCAD**Sas Label:** Local adj HERS like CAD (CAD w/ or w/o stroke & surg or vasc procedure)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Locally adj peripheral arterial disease (PAD)

Locally adjudicated peripheral arterial disease (PAD) (aorta, iliac arteries, or below) requiring and/or occurring during hospitalization. Symptomatic disease including intermittent claudication, ischemic ulcers, or gangrene. Disease must be symptomatic and/or requiring intervention (e.g. vascular or surgical procedure for arterial insufficiency in the lower extremities or abdominal aortic aneurysm).

Variable # 42**Usage Notes:** none**Sas Name:** PAD**Sas Label:** Local adj peripheral arterial disease (PAD)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to PAD

Days from randomization to peripheral arterial disease (PAD)

Variable # 43**Usage Notes:** none**Sas Name:** PADDY**Sas Label:** Days from rand to PAD**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

**Peripheral arterial disease (PAD) diagnosis****Variable #** 44**Usage Notes:** none**Sas Name:** PADDIAG**Sas Label:** PAD diagnosis**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

1	Lower extremity claudication
2	Atherosclerosis of arteries of the lower extremities
3	Arterial embolism and/or thrombosis of the lower extremities
4	Abdominal aortic aneurysm (AAA)

Locally adjudicated lower extremity disease

Locally adjudicated lower extremity disease (claudication, atherosclerosis of arteries, or arterial embolism and/or thrombosis of lower extremities)

Variable # 45**Usage Notes:** none**Sas Name:** LOEXTREM**Sas Label:** Local adj lower extremity disease (claudication, atherosclerosis of arteries, or arterial embolism &/or thrombosis of lower extremities)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values****Locally adjudicated abdominal aortic aneurysm**

Locally adjudicated abdominal aortic aneurysm (with or without surgical or vascular procedure).

Variable # 46**Usage Notes:** none**Sas Name:** AAA**Sas Label:** Local adj abdominal aortic aneurysm (AAA w/ or w/o surg or vasc procedure)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Locally adj HERS like lower extremity disease

Locally adjudicated HERS like lower extremity disease

Variable # 47**Usage Notes:** none**Sas Name:** HERSLOEX**Sas Label:** Local adj HERS like lower extremity disease**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

**Locally adjudicated total CAD and/or PAD**

Locally adjudicated total peripheral arterial disease (CAD and/or PAD)

Variable # 48**Usage Notes:** none**Sas Name:** PVD**Sas Label:** Local adj total peripheral arterial disease (CAD + PAD)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to total CAD and/or PAD

Days from randomization to total peripheral arterial disease (CAD and/or PAD)

Variable # 49**Usage Notes:** none**Sas Name:** PVDDY**Sas Label:** Days from rand to total CAD+PAD**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

Centrally adjudicated deep vein thrombosis (DVT)**Variable #** 50**Usage Notes:** none**Sas Name:** DVT**Sas Label:** Central adj deep vein thrombosis (DVT)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to DVT**Variable #** 51**Usage Notes:** none**Sas Name:** DVTDY**Sas Label:** Days from rand to DVT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

Centrally adjudicated idiopathic DVT

Centrally adjudicated deep vein thrombosis of lower extremities not resulting from a procedure within 60 days.

Variable # 52**Usage Notes:** none**Sas Name:** DVT1**Sas Label:** Central adj idiopathic DVT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

**Days from randomization to idiopathic DVT**

Days from randomization to deep vein thrombosis of lower extremities not resulting from a procedure within 60 days.

Variable # 53**Usage Notes:** none**Sas Name:** DVT1DY**Sas Label:** Days from rand to idiopathic DVT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

Centrally adjudicated secondary DVT

Centrally adjudicated deep vein thrombosis of lower extremities during or following a procedure within 60 days.

Variable # 54**Usage Notes:** none**Sas Name:** DVT2**Sas Label:** Central adj secondary DVT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to secondary DVT

Days from randomization to deep vein thrombosis of lower extremities during or following a procedure within 60 days.

Variable # 55**Usage Notes:** none**Sas Name:** DVT2DY**Sas Label:** Days from rand to secondary DVT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

DVT based on hospital discharge summary

Diagnosis of deep vein thrombosis is based on: Hospital discharge summary with a diagnosis of deep vein thrombosis.

Variable # 56**Usage Notes:** none**Sas Name:** DVTDSCHG**Sas Label:** DVT based on hospital discharge summary**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

DVT based on postive findings on a venogram

Diagnosis of deep vein thrombosis is based on: Positive findings on a venogram.

Variable # 57**Usage Notes:** none**Sas Name:** DVTVENO**Sas Label:** DVT based on postive venogram**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

**DVT based on positive impedance plethysmography**

Diagnosis of deep vein thrombosis is based on: Positive findings using impedance plethysmography.

Variable # 58**Usage Notes:** none**Sas Name:** DVTIMPED**Sas Label:** DVT based on impedance plethysmography**Categories:** Medical History: Cardiovascular Outcome**Type:** Categorical**Values**

0	No
1	Yes

DVT based on positive finding on non-invasive exam

Diagnosis of deep vein thrombosis is based on: Positive findings on doppler duplex, ultrasound, sonogram, or other non-invasive test examination.

Variable # 59**Usage Notes:** none**Sas Name:** DVTNOINV**Sas Label:** DVT based on non-invasive exam**Categories:** Medical History: Cardiovascular Outcome**Type:** Categorical**Values**

0	No
1	Yes

DVT based on positive findings on isotope scan

Diagnosis of deep vein thrombosis is based on: Positive findings on isotope scan.

Variable # 60**Usage Notes:** none**Sas Name:** DVTISOTOP**Sas Label:** DVT based on isotope scan**Categories:** Medical History: Cardiovascular Outcome**Type:** Categorical**Values**

0	No
1	Yes

Diagnosis of DVT reporting source**Variable #** 61**Usage Notes:** none**Sas Name:** DVTREPT**Sas Label:** DVT diagnosis reporting source**Categories:** Medical History: Cardiovascular Outcome**Type:** Categorical**Values**

1	Hospital inpatient
2	Hospital outpatient facility or clinic
3	Radiology or imaging facility
4	Physician's office/private medical practitioner
5	Nursing/convalescent home/hospice
6	Autopsy only
7	Death certificate only
8	Other

**Work up for pulmonary embolism (PE) performed**

Variable # 62

Usage Notes: none

Sas Name: PEWORKUP

Sas Label: Work- up for PE performed

Categories: Medical History: Cardiovascular
Outcome

Type: Categorical

Values

0	No
1	Yes
8	Unknown

Centrally adjudicated pulmonary embolism (PE)

Centrally adjudicated pulmonary embolism (PE) requiring hospitalization.

Variable # 63

Usage Notes: none

Sas Name: PE

Sas Label: Central adj pulmonary embolism (PE)

Categories: Medical History: Cardiovascular
Outcome: Adjudicated

Type: Categorical

Values

0	No
1	Yes

Days from randomization to pulmonary embolism (PE)

Variable # 64

Usage Notes: none

Sas Name: PEDY

Sas Label: Days from rand to PE

Categories: Medical History: Cardiovascular
Outcome: AdjudicatedType: Continuous

Centrally adjudicated idiopathic PE

Centrally adjudicated pulmonary embolism (PE) not resulting from a procedure within 60 days.

Variable # 65

Usage Notes: none

Sas Name: PE1

Sas Label: Central adj idiopathic PE

Categories: Medical History: Cardiovascular
Outcome: Adjudicated

Type: Categorical

Values

0	No
1	Yes

Days from randomization to idiopathic PE

Days from randomization to pulmonary embolism (PE) not resulting from a procedure within 60 days.

Variable # 66

Usage Notes: none

Sas Name: PE1DY

Sas Label: Days from rand to idiopathic PE

Categories: Medical History: Cardiovascular
Outcome: AdjudicatedType: Continuous

**Outcomes - CVD (Forms 121, 126, 132)****Data File:** ocvd_ep_fu_pub**File Date:** 04/06/2006 **Structure:** One row per participant**Population:** E+P participants

Centrally adjudicated secondary PE

Centrally adjudicated pulmonary embolism (PE) during or following a procedure within 60 days

Variable # 67**Usage Notes:** none**Sas Name:** PE2**Sas Label:** Central adj secondary PE**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

Days from randomization to secondary PE

Days from randomization to pulmonary embolism (PE) during or following a procedure within 60 days

Variable # 68**Usage Notes:** none**Sas Name:** PE2DY**Sas Label:** Days from rand to secondary PE**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

PE based on hospital discharge summary

Diagnosis of pulmonary embolism is based on: Hospital discharge summary with a diagnosis of pulmonary embolism.

Variable # 69**Usage Notes:** none**Sas Name:** PEDSCHG**Sas Label:** PE based on hospital discharge summary**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

PE based on ventilation-perfusion lung scan

Diagnosis of pulmonary embolism is based on: High probability on ventilation-perfusion lung scan (exclude moderate, intermediate, or low probability on ventilation-perfusion lung scan).

Variable # 70**Usage Notes:** none**Sas Name:** PELNGSCAN**Sas Label:** PE based on ventilation-perfusion lung scan**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

**PE based on pulmonary angiogram or spiral CT**

Diagnosis of pulmonary embolism is based on: Positive findings on pulmonary angiogram or spiral CT.

Variable # 71**Usage Notes:** none**Sas Name:** PEANGIO**Sas Label:** PE based on pulmonary angiogram**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

PE based on DVT and signs suggestive of PE

Diagnosis of pulmonary embolism is based on: Diagnosis of deep vein thrombosis (DVT) based on ≥ 1 DVT criteria, plus signs and symptoms suggestive of PE (e.g., acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest x-ray findings suggestive of PE).

Variable # 72**Usage Notes:** none**Sas Name:** PESUGGEST**Sas Label:** PE based on suggestive signs & DVT**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

PE based on other, including autopsy

Diagnosis of pulmonary embolism is based on: Other, including autopsy.

Variable # 73**Usage Notes:** none**Sas Name:** PEOTHER**Sas Label:** PE based on other, including autopsy**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

0	No
1	Yes

Centrally adjudicated venousthromboembolism

Centrally adjudicated venousthromboembolism (VT: DVT and/or PE).

Variable # 74**Usage Notes:** none**Sas Name:** VTE**Sas Label:** Central adj venousthromboembolism (VT: PE &/or DVT)**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

**Days from randomization to VT**

Days from randomization to venousthromboembolism (VT: DVT and/or PE).

Variable # 75**Usage Notes:** none**Sas Name:** VTEDY**Sas Label:** Days from rand to VT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

Centrally adjudicated idiopathic VT

Centrally adjudicated VT not resulting from a procedure within 60 days.

Variable # 76**Usage Notes:** none**Sas Name:** VTE1**Sas Label:** Central adj idiopathic VT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to idiopathic VT

Days from randomization to VT not resulting from a procedure within 60 days.

Variable # 77**Usage Notes:** none**Sas Name:** VTE1DY**Sas Label:** Days from rand to idiopathic VT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

Centrally adjudicated secondary VT

Centrally adjudicated VT during or following a procedure within 60 days

Variable # 78**Usage Notes:** none**Sas Name:** VTE2**Sas Label:** Central adj secondary VT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to secondary VT

Days from randomization to VT during or following a procedure within 60 days

Variable # 79**Usage Notes:** none**Sas Name:** VTE2DY**Sas Label:** Days from rand to secondary VT**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Continuous

**Centrally adjudicated stroke**

Centrally adjudicated stroke requiring and/or occurring during hospitalization: Rapid onset of a persistent neurologic deficit attributable to an obstruction or rupture of the arterial system (including stroke occurring during or resulting from a procedure)*. Deficit is not known to be secondary to brain trauma, tumor, infection, or other cause. Deficit must last more than 24 hours, unless death supervenes or there is a demonstrable lesion compatible with acute stroke on CT or MRI scan.

*A stroke is defined as procedure-related if it occurs within 24 hours after any procedure or within 30 days after a cardioversion or invasive cardiovascular procedure

Variable # 80**Usage Notes:** none**Sas Name:** STROKE**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Central adj stroke**Type:** Categorical**Values**

0	No
1	Yes

Days from randomization to stroke**Variable #** 81**Usage Notes:** none**Sas Name:** STROKEDY**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Sas Label:** Days from rand to stroke**Type:** Continuous

Stroke diagnosis**Variable #** 82**Usage Notes:** none**Sas Name:** DIAGNOSIS**Categories:** Medical History: Cardiovascular
Outcome**Sas Label:** Stroke diagnosis**Type:** Categorical**Values**

0	No stroke
1	Subarachnoid hemorrhage
2	Intraparenchymal hemorrhage
3	Other or unspecified intracranial hemorrhage (nontraumatic)
4	Occlusion of cerebral or pre-cerebral arteries with infarct
5	Acute, but ill-defined, cerebrovascular disease
6	Central-nervous system complications
7	Report of cerebrovascular death only

Oxfordshire classification**Variable #** 83**Usage Notes:** none**Sas Name:** OXFORD**Categories:** Medical History: Cardiovascular
Outcome**Sas Label:** Oxfordshire classification**Type:** Categorical**Values**

1	Total anterior circulation infarct (TACI)
2	Partial anterior circulation infarct (PACI)
3	Lacunar infarction (LACI)
4	Posterior circulation infarct (POCI)

**TOAST classification**

Trial of Org 10172 in Acute Stroke Treatment (TOAST) Classification

Variable # 84**Usage Notes:** none**Sas Name:** TOAST**Sas Label:** Toast classification**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

1	Probable large artery atherosclerosis (embolus/thrombosis)
2	Probable cardioembolism (high-risk/medium risk)
3	Probable small vessel occlusion (lacune)
4	Probable stroke of other determined etiology
5	Possible large artery atherosclerosis (embolus/thrombosis)
6	Possible cardioembolism (high-risk/medium risk)
7	Possible small vessel occlusion (lacune)
10	Possible stroke of other determined etiology
11	Stroke of undetermined etiology: 2 or more causes identified
12	Stroke of undetermined etiology: Negative evaluation
13	Stroke of undetermined etiology: Incomplete evaluation

Glasgow outcome scale

Participant's functional status at the time of hospital discharge for stroke (Glasgow Outcome Scale)

Variable # 85**Usage Notes:** none**Sas Name:** GLASGOW**Sas Label:** Glasgow outcome scale**Categories:** Medical History: Cardiovascular
Outcome**Type:** Categorical**Values**

1	Good recovery
2	Moderately disabled
3	Severely disabled
4	Vegetative survival
5	Dead
6	Unable to categorize stroke

MI, coronary death, PTCA, CABG, or angina**Variable #** 86**Usage Notes:** none**Sas Name:** TOTCHD**Sas Label:** MI, coronary death, PTCA, CABG, or angina**Categories:** Medical History: Cardiovascular
Outcome: Adjudicated**Type:** Categorical**Values**

0	No
1	Yes



Outcomes - CVD (Forms 121, 126, 132)

Data File: ocvd_ep_fu_pub

File Date: 04/06/2006

Structure: One row per participant

Population: E+P participants

Days from rand to MI, cor. death, PTCA, CABG, ang

Days from randomization to first occurrence of MI, coronary death, PTCA, CABG, or angina

Variable # 87

Usage Notes: none

Sas Name: TOTCHDDY

Sas Label: Days from rand to MI, coronary death, PTCA, CABG, or angina

Categories: Medical History: Cardiovascular
Outcome: Adjudicated

Type: Continuous
